# EV426999744US 12-07-06

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| YFE   |                           | Application Number   | 09/7/19,410                  | )                      |  |   |
| RANSMITTAL  | Filing Date               | 12-Dec-200   | 12-Dec-2000                  |                        |  |   |
| 0 5 2006 w FORM   | First Named Inventor      | GOKE, Bui  | GOKE, Burkhard, et al.       |                        |  |   |
| <i>[                                    </i>  |                           | Art Unit   | 1654                         |                        |  |   |
|   |                           | Examiner Name  | MOHAME                       | D. Abdel A             | ۸.   |   |
| RAD abe used for all correspondence after initial   |                           | Attorney Docket Number   | +                            |                        |  |   |
| Total Number of Pages in This Submission  | 162                       |  | 0206-UTL-                    | <del></del>            |  |   |
|   | ENCL                      | OSURES (Check al   | I that apply                 | )                      |  |   |
| Fee Transmittal Form  Fee Attached  Amendment/Reply  After Final  Affidavits/declaration(s)  Extension of Time Request  Express Abandonment Request  Information Disclosure Statement  Certified Copy of Priority Document(s)  Reply to Missing Parts/ Incomplete Application  Reply to Missing Parts |                           | Prawing(s)  icensing-related Papers  Petition Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence Ferminal Disclaimer Request for Refund CD, Number of CD(s)  Landscape Table on C | Address                      | Cited                  | Appea<br>of App<br>Appea<br>(Appea<br>Proprie<br>Status<br>Other<br>below) | Enclosure(s) (please Identify                                   |
| under 37 CFR 1.52 or 1.53   | TURE O                    | F APPLICANT, ATTO  | ORNEY, C                     | R AGI                  | ENT  | •   |
| Firm Name Amylin Pharmaceuticals,   |                           | <u>.</u>   |                              |                        |  |   |
| Signature C   | P                         |  |                              | ···                    |  |   |
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| Printed name BUTLER, Vames E.   |                           |  |                              |                        | _  |   |
| Date 5-Dec-2006   |                           |  | Reg. No.                     | 40,931                 |  |   |
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| I hereby certify that this correspondence is b sufficient postage as first class mail in an en the date shown below:  | eing facsir<br>velope add | mile transmitted to the USP<br>dressed to: Commissioner f  | TO or depos<br>or Patents, F | sited with<br>P.O. Box | the Un<br>1450, /  | ited States Postal Service with<br>Alexandria, VA 22313-1450 on |
| Signature XIII.C. Solomon   |                           |  |                              |                        |  |   |
| Typed or printed name Kelly B. Solomor  |                           | ,-31.0 <b>4</b> 1  |                              | Date 6-Dec-2006        |  |   |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

application of:

GOKE, et al

Art Unit:

1654

Appln. No.: 09/719,410

Examiner:

Mohamed, A.

Filed:

12-Dec-2000

Atty. Docket:

0206-UTL-9

For:

GLUCAGON-LIKE PEPTIDE-1 IMPROVES

BETA-CELL RESPONSE TO GLUCOSE IN SUBJECTS WITH IMPARIED GLUCOSE

TOLERANCE (AMENDED)

Confirm. No.:

8826

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, Applicant submits copies of the references listed on the attached PTO Form PTO/SB/08A for consideration by the U.S. Patent and Trademark Office in the above-entitled application and to be made of record herein. In accordance with 37 C.F.R. 1.98, copies of cited U.S. Patents and U.S. Patent Application Publications are not included herewith. Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08A, indicating that the information has been considered and made of record herein.

I certify that each item contained in this Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application

#### CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. 1.10

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being deposited with the United States Postal Service for "Express Mail Post Office to Addressee" service, Express Mail Label No. EV426999744,in an envelope addressed to the Commissioner for Patents, Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

> Person Mailing Paper Signature of Person Mailing Paper

5-Dec-06

Date of Deposit

not more than three months prior to the filing of this Statement. A copy of the Japanese Search Report dated September 5, 2006 is enclosed.

It is respectfully noted that Applicant is submitting only those references cited in the Japanese Search Report that were not previously submitted with the Information Disclosure Statement filed on March 6, 2001.

In the event any fee is deemed necessary upon the filing of the attached Supplemental Information Disclosure Statement, the Commissioner is hereby authorized to charge any such fee which may be required during the pendency of this application to Account No. 010535. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

> Respectfully submitted, AMYLIN PHARMACEUTICALS, INC.

Dated: 5-Dec-06

Registration No. 40,931

AMYLIN PHARMACEUTICALS, INC. 9360 Towne Centre Drive San Diego, CA 92121 Telephone: 858.552.2200

Facsimile: 858.552.1936

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Sheet 1

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| Complete it Known      |                   |  |  |  |
|------------------------|-------------------|--|--|--|
| Application Number     | 09/719,410        |  |  |  |
| Filing Date            | 12-Dec-2000       |  |  |  |
| First Named Inventor   | GOKE, Burkhard    |  |  |  |
| Art Unit               | 1654              |  |  |  |
| Examiner Name          | Mohamed, Abdel A. |  |  |  |
| Attorney Docket Number | 0206-UTL-9        |  |  |  |

|                       |  |  | U. S. PATENT D                 | OCUMENTS   |   |
|-----------------------|--|--|--------------------------------|--|---|
| Examiner<br>Initials* | Cite<br>No.1                                     | Document Number  Number-Kind Code <sup>2 (# known)</sup> | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
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|-----------------------|--------------|---|---------------------|--|---|---|
| Examiner<br>Initials* | Cite<br>No.1 | Foreign Patent Document   | Publication<br>Date | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages |   |
|                       |              | Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>5</sup> (if known) | MM-DD-YYYY          |  | Or Relevant Figures Appear                        |   |
| _                     | 1            | WO 97/46584   | 12-11-1997          | Boehringer Mannheim GMBH                           |   |   |
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|                       |              |   |                     |  |   |   |
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| Examiner  | Date       |   |  |
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| Signature | Considered | 1 |  |
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B (07-05)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE tinde the Paperalling Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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| INF      |                    | DIS       | CLOSURE   | Filing Date            |                   |  |
| STA      | TEMENT E           | BY A      | PPLICANT  | First Named Inventor   |                   |  |
|          |                    |           |           | Art Unit               |                   |  |
|          | (Use as many sh    | eets as r | ecessary) | Examiner Name          |                   |  |
| Sheet    | 2                  | of        | 2         | Attorney Docket Number |                   |  |

|                       |                          | NON PATENT LITERATURE DOCUMENTS   |                |
|-----------------------|--------------------------|---|----------------|
| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                       | 2                        | BYRNE - GLP-1 Improves First Phase Insulin Secretion without Altering Insulin Sensitivity in Subject with Impaired Glucose Tolerance; Diabetes; Volume 47; Abstract 0744, Page A192, (May-1998)   |                |
|                       | 3                        | BYRNE - Human Studies with Glucagon-like-Peptide-1: Potential of the Gut Hormone for Clinical Use; Diabetes Medicine, Vol. 13; Issue 10; pages 854-860 (Oct-1996)   |                |
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| Examiner  | Date       |  |
|-----------|------------|--|
| Signature | Considered |  |

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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